

REMARKS

The instant invention relates in part to supports on which an assay for one or more analytes can be performed. In particular, the claimed invention relates to supports that are configured to capture analytes on a surface for detection, preferably by optical assay methods, through the use of an attachment layer comprising diamond-like carbon.

Prior to the present communication, Claims 51-91 were pending in the instant application, with Claims 51-82 under examination, and Claims 83-91 withdrawn from consideration by the Examiner. By the present communication, Applicants have cancelled Claims 83-91, and amended Claims 63 and 79. The amended claims are fully supported by the specification, and do not introduce new matter or require a new search. The amendments simply clarify the claimed invention using preferred terminology, and are not intended to further limit the claim, and should not be taken to do so.

Notwithstanding the foregoing, Applicants expressly reserve the right to pursue subject matter no longer claimed in the instant application in one or more applications which may claim priority hereto. Applicants respectfully request reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non-Art Related Remarks

35 U.S.C. §112, 2nd paragraph

Claims 63 and 79 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for the recitation of an abbreviation "PETE" in the claims. Applicants respectfully submit that the abbreviation "PETE" has been amended to read "polyethylene terephthalate," thus rendering the rejection moot.

Art Related Remarks

35 U.S.C. §102

Applicants respectfully traverse the rejection of Claims 51, 52, 55-60, 66-68, 71-76 and 82 under 35 U.S.C. § 102(e) as allegedly being anticipated by Kobashi, U.S. Patent No. 5,777,372, filed 1 March 1996 ("the '372 patent").

In order to anticipate a claim, a single prior art publication must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teachings of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also* MPEP §2131.

With respect to Claims 51-52, 55-60 and 66, the rejected claims relate to an assay support comprising an attachment layer comprising diamond-like carbon ("DLC"), in which the attachment layer is adapted to directly bind an analyte of interest to the DLC for detection in an assay. As noted in the instant specification, *e.g.*, on page 19, lines 20-25, the presence of an analyte-specific binding layer is optional. These claims refer to assay supports in which no analyte-specific binding agent is present; thus, the analyte is directly bound by the diamond-like carbon. In such embodiments in which the analyte is nonspecifically captured, a subsequent analyte-specific reagent may be used to specifically determine the presence or amount of analyte.

The Examiner is incorrect that the '372 patent discloses "capture of the analyte of interest... by binding the analyte directly to the diamond-like carbon." Paper No. 11, page 4. Instead, in the '372 patent analyte is always captured by a "bioidentifier" that is itself bound to the diamond-like carbon. *See, e.g.*, Column 10, lines 29-31 and 63-67. It is respectfully submitted that the '372 patent does not teach or suggest an assay support having an attachment layer as described in instant Claims 51-52, 55-60 and 66.

With respect to Claims 67-68, 71-76 and 82, which do comprise a separate capture molecule on the diamond-like carbon, the '372 patent does not disclose an attachment layer comprised of diamond-like carbon between about 50 Å and about 500 Å as required by these

claims. The Examiner refers with particularity to measurements in column 7, lines 10-22, of the '372 patent, which refers to a "diamond base layer" having a thickness of between 0.1 and 50 μm , as disclosing "a layer of diamond-like carbon of between about 50 \AA to about 3000 \AA ." Paper No. 11, page 5. As 1 $\text{\AA} = 10^{-10}$ m, or 0.1 nm, the range referred to in the '372 patent is 1,000 - 500,000 \AA , which is not overlapping with the claimed range of between about 50 \AA and about 500 \AA .

Applicants also respectfully disagree that the '372 patent discloses any "optically functional layer" on a support, or that the support provides a change in optical thickness upon analyte binding. As described on page 10, lines 4-23, the term "optically functional layer" as used in the present claims refers to a layer that can produce a signal upon binding of an analyte to a receptive layer on the optically functional layer. Generation of the signal is due to changes in one or more optical properties of the optically functional layer mediated by a mass change resulting from analyte binding. Examples of such changes in optical properties include attenuation of one or more wavelengths of light; extinction or enhancement of specific wavelengths; modification of intensity of specific wavelengths; or modification of the state or degree of polarization, *etc.* See, *e.g.*, page 8, lines 15-18, and page 15, line 9, through page 16, line 2. This change in optical properties mediated solely by a change in the thickness of a mass layer on the device surface is referred to in the instant specification as a change in "optical thickness."

In contrast, the devices in the '372 patent rely on the electronic properties, and not the optical properties, of diamond film to generate a signal. Thus, the '372 patent discloses a biosensor that is composed of a photosensitive transducer that detects changes in light reaching the diamond layer. This light is detected by monitoring electronic changes using the diamond film as a photodetector. See, *e.g.*, '372 patent, column 10, lines 14-31. But no optical properties of the device layers are modified by a mass change in the devices of the '372 patent. Therefore, the '372 patent does not provide any change in optical thickness upon analyte binding.

Applicants also respectfully disagree that the '372 patent discloses any devices configured to provide laminar flow across the support. The term "laminar flow" is a well understood term of art. Because the '372 patent never refers to laminar flow through or across a device, Applicants

assume that the Examiner is arguing that flow across the devices shown in Figures 7-15 is inherently laminar. Applicants respectfully note that the mere fact that such a characteristic may occur is not sufficient to establish inherency. Rather, the Examiner must establish that the characteristic necessarily occurs. *See, e.g.*, MPEP §2112. Applicants respectfully request that the Examiner provide extrinsic evidence making it clear that the missing descriptive matter from the claims is necessarily present in the devices disclosed in the '372 patent.

Because the '372 patent does not teach each and every element set forth in the claims, no *prima facie* case of anticipation has been established. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 53, 54, 69 and 70 under 35 U.S.C. §103(a), as allegedly being unpatentable over Kobashi, US Patent No. 5,777,372 ("the '372 patent") in view of Yu, US Patent No. 5,273,788 ("the '788 patent"); claims 61-63 and 77-79 as allegedly being unpatentable over the '372 patent in view of Turner *et al.*, US Patent No. 5,624,537 ("the '537 patent"); and claims 64, 65, 80 and 81 as allegedly being unpatentable over the '372 patent in view of Choi *et al.*, US Patent No. 5,883,769 ("the '769 patent").

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited publications or in knowledge available to the ordinarily skilled artisan, to modify or combine the publications; there must be a reasonable expectation of success in combining the publications; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) See also MPEP §2143.

As discussed above, the '372 patent does not disclose a support that comprises an attachment layer comprising diamond-like carbon that is adapted to directly bind an analyte of interest for detection in an assay, as required by independent Claim 51 and its dependent claims; an attachment layer comprised of diamond-like carbon between about 50 Å and about 500 Å as

required by independent Claim 67 and its dependent claims; an "optically functional layer" on a support; or devices configured to provide laminar flow across the support.

The Examiner has provided no reasoning as to why the skilled artisan would be motivated to provide such elements in a device, as the Examiner has incorrectly asserted that each element of the claims is provided by the '372 patent. Thus, Applicants respectfully submit that no *prima facie* case of obviousness has been established for the rejected claims. Applicants respectfully submit that this flaw in the purported *prima facie* case is not cured by combining the '372 patent with any of the secondary references cited by the Examiner, as each secondary reference is cited for a reason that is unrelated to the foregoing elements absent from the *prima facie* case. For example, with regard to the '788 patent, this publication is cited for allegedly disclosing "variations in sp^2 and sp^3 characteristics which determine the hydrophobicity" and the "antireflective" nature of diamond-like carbon films (Paper No. 11, page 7); with regard to the '537, this publication is cited for allegedly disclosing "cellulose and filter paper" (Paper No. 11, page 9); and with regard to the '769 patent, this publication is cited for allegedly disclosing "the hardness of diamond-like carbon" (Paper No. 11, page 11).

Moreover, with regard to the asserted reasoning for combination of the '372 patent with the secondary '788 patent, the '372 patent discloses only that the hydrophobicity of diamond may be controlled by chemical treatment. *See, e.g.*, '372 patent, column 5, lines 29-32. Nothing in the '788 patent indicates that it would be either desirable or even possible to determine the hydrophobicity of an attachment layer by preselecting the sp^2 and sp^3 character of the diamond-like carbon, as required by instant claims 53 and 69. Thus, the skilled artisan would not be motivated to preselect the sp^2 and sp^3 characteristics of the diamond-like carbon layer.

Further, while the Examiner asserts, based on the '788 patent, that antireflection is "necessarily present in the diamond-like carbon of [the '372 patent]," Applicants respectfully submit that this position is not supported by any objective evidence of record, as nothing of record indicates that diamond-like carbon layers are inherently anti-reflective. Antireflective coatings are very well known in the optical arts. In order to function, the thickness of an

antireflective layer must be an odd number of quarter wavelengths (relative to the incident light) in order to achieve reflections that are π radians out of phase to provide the cancellation required for antireflection. Furthermore, light reflected from the outer layer of the anti-reflection coating and light reflected from the surface of the substrate must have the same intensity in order to cancel one another. In contrast, the substrate surface in the '372 patent is designed to absorb light (thereby generating an electronic signal), and would thus not be compatible with the provision of an antireflective layer. Applicants respectfully request that the Examiner provide extrinsic evidence making it clear that the missing descriptive matter from the claims is necessarily present in the devices disclosed in the '372 patent, as the Examiner contends.

With regard to the combination of the '372 patent with the secondary '537 patent, the Examiner's contention that "biosensors comprising the claimed cellulose and filter paper were well known in the art," and that such materials would "[provide] efficient and reliable feedback control" (Paper No. 11, pages 9-10) does not provide a motivation to combine the '537 patent with the '372 patent. The cellulose matrix of the '537 patent functions, with a cellulose binding domain ("CBD") from a particular bacterium, to provide a "protein receiving matrix." Nothing in this patent, however, indicates that cellulose would be appropriate as a support underlying a diamond-like carbon layer, where the "protein receiving" purpose would be irrelevant. Rather than providing "particular findings... as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed" (*In re Kotzab*, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000)), the rejection simply identifies the elements of the claim in different publications, and asserts that it would be obvious to combine them. An obviousness rejection cannot be premised on such a *post hoc* hindsight analysis.

Finally, with regard to the combination of the '372 patent with the secondary '769 patent, Applicants respectfully submit that the production of aluminum heads for use in video cassette recorders as described in the '769 patent is non-analogous art that would not be considered reasonably pertinent to problems in biosensor design. Again, the rejection simply identifies the elements of the claim in different publications, and asserts that it would be obvious

to combine them, and an obviousness rejection cannot be premised on such a *post hoc* hindsight analysis.

Because the cited references, alone or in combination, fail to teach or suggest all of the limitations set forth in the instant claims, and because nothing in the Examiner's alleged *prima facie* case provides any motivation to modify the devices of the cited references to provide the instantly claimed invention, Applicants respectfully request that the rejections under 35 U.S.C. §103 be reconsidered and withdrawn.

Double Patenting

The Examiner has provisionally rejected claims 51-82 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7, 11, 23-34 and 38-50 of copending U.S. Application No. 08/950,963. Applicants respectfully submit that, because the instant claims are in allowable form, the provisional double patenting rejection is the only remaining rejection in the instant application. As such, the examiner should withdraw the rejection and permit the claims to issue. *See, e.g.*, MPEP 804(I)(B).

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

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